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Cranial Electrotherapy Stimulation (CES) in Soldiers with Insomnia: A Pilot Study

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6. AUTHOR(S)

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N/A

14. ABSTRACT

Purpose: 1. Test feasibility and acceptability of Cranial Electrotherapy Stimulation (CES) for insomnia. 2. Evaluate extent of change in pre- and post-treatment sleep measures.

Design: A double-blind randomized controlled, parallel design to compare the effect of CES to Sham.

Methods: Subjects received 10 intervention sessions over a 2-week period (randomized to Active CES or Sham treatment) and completed 1-month follow-up surveys. Subjects completed questionnaires at baseline, immediately after treatment, and one month after treatment. Sleep diaries were recorded for 1 week prior to intervention, concurrently during the 2 weeks of intervention, and for 1 week at the 1-month follow-up.

Sample: A convenience sample of military beneficiaries with insomnia in a non-deployed environment.

Analysis: 1. Feasibility and acceptability were assessed through comparing the number of subjects and missed sessions throughout the study, as well as by participant expectancy. 2. To evaluate the extent of change pre- and post-treatment sleep measures, both a 2 x 2 and a 2 x 3 mixed ANOVA were conducted.

Findings: 1. 27 of 230 individuals screened were allocated to the intervention, of which 3 withdrew; thus, 24 were randomized to CES or Sham groups. For acceptability, the CES group had significantly higher means than the Sham group for 2 of 4 expectancy items. 2. Overall, the self-reported extent of change as measured by the total Insomnia Severity Index (ISI) score and sleep parameters of Pittsburgh Sleep Diary, though not significant, had a more appreciable improvement over time for the CES group.

15. SUBJECT TERMS

Cranial Electrotherapy Stimulation (CES), insomnia, post-treatment sleep, sleep diary, Military

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USU Grant Number	HU0001-11-1-TS12
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Period of Award	1 August 2011 – 31 March 2016
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Address of Applicant Organization	917 Pacific Ave, Suite 600, Tacoma WA 98402

Principal Investigator (PI) Military Contact Information

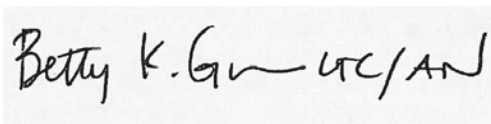Duty Title ███████████████████████████████

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Table of Contents

Abstract

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Implications for Military Nursing: Although the trends showed an overall improvement in self-reported sleep measures, the feasibility of recruiting subjects with pure insomnia provided a challenge in achieving adequate numbers for statistical relevance. Other lessons learned included optimization of recruitment and communication methods based on the movement of the military community.

TSNRP Research Priorities that Study or Project Addresses

Primary Priority

Force Health Protection:	☒ Fit and ready force ☐ Deploy with and care for the warrior ☐ Care for all entrusted to our care
Nursing Competencies and Practice:	☐ Patient outcomes ☐ Quality and safety ☐ Translate research into practice/evidence-based practice ☐ Clinical excellence ☐ Knowledge management ☐ Education and training
Leadership, Ethics, and Mentoring:	☐ Health policy ☐ Recruitment and retention ☐ Preparing tomorrow's leaders ☐ Care of the caregiver
Other:	☐

Secondary Priority

Force Health Protection:	☐ Fit and ready force ☐ Deploy with and care for the warrior ☒ Care for all entrusted to our care
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Leadership, Ethics, and Mentoring:	☐ Health policy ☐ Recruitment and retention ☐ Preparing tomorrow's leaders ☐ Care of the caregiver
Other:	☐

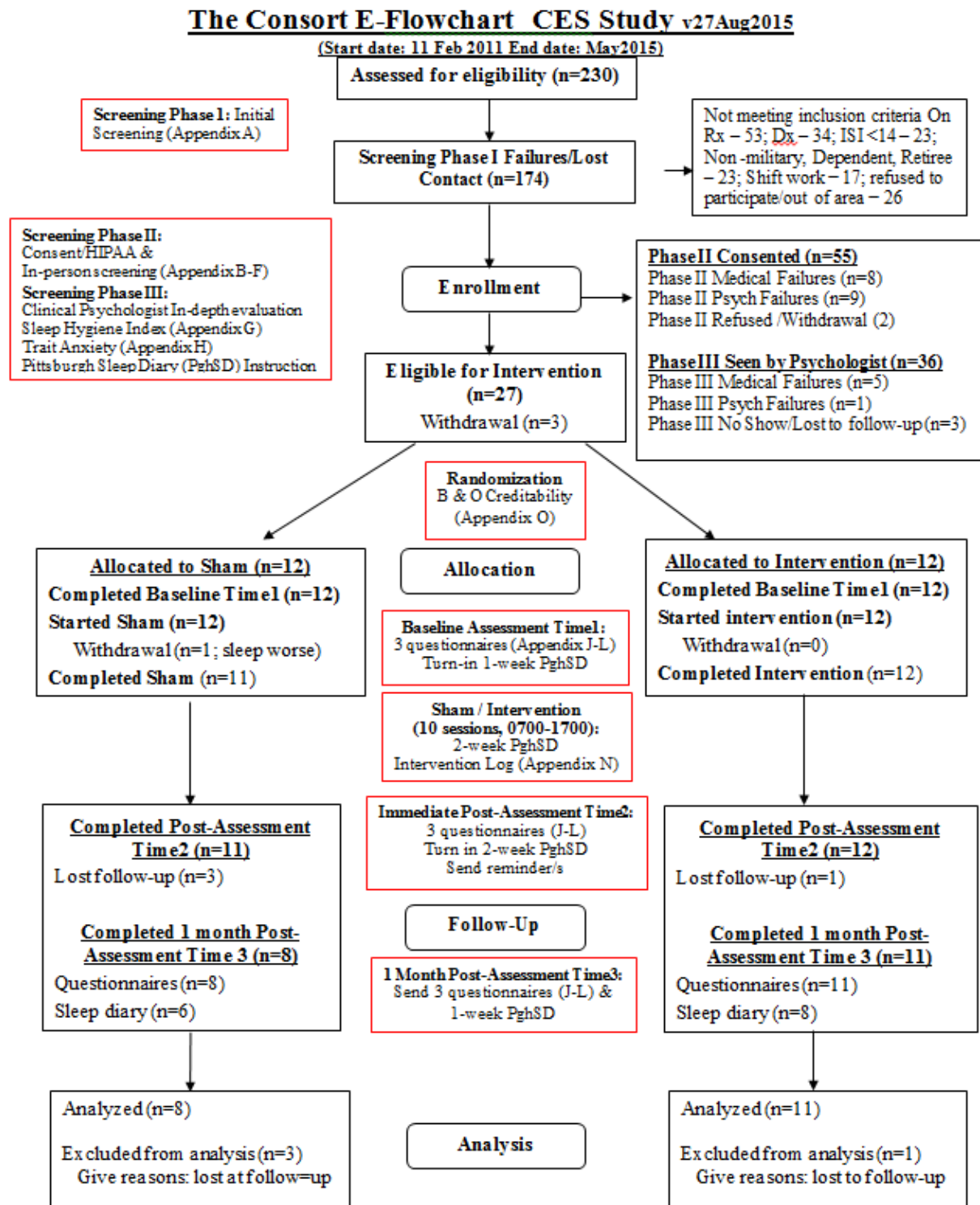**Progress Towards Achievement of Specific Aims of the Study or Project**

Findings related to each specific aim, research or study questions, and/or hypothesis:

Question #1: Is conducting CES therapy feasible (e.g. recruitment, prescreening, consent, randomization, and retention) and acceptable (e.g. number of missed sessions and participant expectancy) treatment protocol for soldiers with insomnia?

Feasibility was assessed using the number of subjects who completed the phone screen, met the eligibility screening, returned the questionnaires, and completed the study.
- Recruitment began in February 2011, was put on hold from July 2011 to July 2012 due to deployment of the PI, and then continued through December 2014 until very few potential subjects would call to be screened and none were deemed eligible.
- Of 230 screened, 174 were screening failures or lost to contact. Of the 55 who consented, 17 were screening failures and 2 withdrew. Of the 36 screened by the psychologist, 6 were screening failures, and 3 were no-shows or lost to follow-up. Of the 27 allocated to the intervention, 3 subjects withdrew prior to the start of the intervention. Of the 24 that completed the baseline assessments at Time1 and started the intervention, 1 withdrew during the intervention due to worsening of sleep disturbance. Thus, 23 completed the immediate post-assessment at Time2. Of these 19 out of 23 completed the 1-month post-assessment at Time3 as 4 were lost after Time2. Of the 19 who completed Time3, all completed the questionnaires but only 14 completed the sleep diary. Thus, a total of 14 participants, out of a goal of 50, completed all data collection phases of the study. See Diagram 1.

Diagram 1. CES Consort Flowchart

The Consort E-Flowchart CES Study v27Aug2015
(Start date: 11 Feb 2011 End date: May2015)

Assessed for eligibility (n=230)

Screening Phase 1: Initial Screening (Appendix A)

Screening Phase I Failures/Lost Contact (n=174)

Not meeting inclusion criteria On Rx − 53; Dx − 34; ISI <14 − 23; Non -military, Dependent, Retiree − 23; Shift work − 17; refused to participate/out of area − 26

Screening Phase II: Consent/HIPAA & In-person screening (Appendix B-F)
Screening Phase III: Clinical Psychologist In-depth evaluation Sleep Hygiene Index (Appendix G) Trait Anxiety (Appendix H) Pittsburgh Sleep Diary (PghSD) Instruction

Enrollment

Phase II Consented (n=55)
Phase II Medical Failures (n=8)
Phase II Psych Failures (n=9)
Phase II Refused /Withdrawal (2)

Phase III Seen by Psychologist (n=36)
Phase III Medical Failures (n=5)
Phase III Psych Failures (n=1)
Phase III No Show/Lost to follow-up (n=3)

Eligible for Intervention (n=27)
Withdrawal (n=3)

Randomization B & O Creditability (Appendix O)

Allocated to Sham (n=12)
Completed Baseline Time1 (n=12)
Started Sham (n=12)
   Withdrawal (n=1; sleep worse)
Completed Sham (n=11)

Allocation

Baseline Assessment Time1: 3 questionnaires (Appendix J-L) Turn-in 1-week PghSD

Allocated to Intervention (n=12)
Completed Baseline Time1 (n=12)
Started intervention (n=12)
   Withdrawal (n=0)
Completed Intervention (n=12)

Sham / Intervention (10 sessions, 0700-1700): 2-week PghSD Intervention Log (Appendix N)

Completed Post-Assessment Time2 (n=11)
Lost follow-up (n=3)

Immediate Post-Assessment Time2: 3 questionnaires (J-L) Turn in 2-week PghSD Send reminder/s

Completed Post-Assessment Time2 (n=12)
Lost follow-up (n=1)

Completed 1 month Post-Assessment Time 3 (n=8)
Questionnaires (n=8)
Sleep diary (n=6)

Follow-Up

1 Month Post-Assessment Time3: Send 3 questionnaires (J-L) & 1-week PghSD

Completed 1 month Post-Assessment Time 3 (n=11)
Questionnaires (n=11)
Sleep diary (n=8)

Analyzed (n=8)
Excluded from analysis (n=3) Give reasons: lost at follow=up

Analysis

Analyzed (n=11)
Excluded from analysis (n=1) Give reasons: lost to follow-up

6

Acceptability was assessed by the number of missed sessions and participant expectancy.
- Only 1 participant from the Sham group withdrew during the intervention after stating that sleep was getting worse. One participant did not complete the 1-month follow-up visit (ISI and sleep diary) and an additional 8 did not complete the final sleep diary.
- Expectancy was measured by the four items extracted from the Borkovec and Nau (B & N) Questionnaire and the two groups (CES vs. Sham) were compared. Significant between group differences were found for two of the items (via both parametric and nonparametric testing) with the CES group obtaining higher means (and mean ranks) than the Sham group on the following items: (a) "how logical is the treatment" ($Z = -2.62$, $p = .009$) and (b) "Recommend this treatment to a friend" ($Z = -2.41$, $p = .016$).

Question #2: Does the use of CES improve the immediate and short-term effects (1 month after treatment) on pre-and post-treatment self-reported sleep outcomes as measured by the total Insomnia Severity Index score and sleep parameters of Pittsburgh Sleep Diary (sleep efficiency, sleep onset latency, number of awakenings, wake after sleep onset, and overall sleep quality)?

The focus of the analysis was on comparing the two groups: Active (CES Treatment) vs. Sham (control) across three phases of measurement: baseline (Time1; Active n = 12 and Sham n = 12), immediate after treatments/post-assessment (Time2; Active n = 12 and Sham n = 11) and 1-month post-assessment (Time3; Active n = 11 and Sham n = 8). Given missing data at the last phase of data collection (1 ISI and 9 sleep diaries), the summary of results includes both a 2 x 2 (first two phases, Time1 and Time2) and 2 x 3 (all three phases, Tim1-Time3) analysis.

- The two-way interaction for the **summed ISI total score** is not significant: $F(1,21) = 1.39$, $p = .251$ ($\eta^2 = .062$). The main effect for time is significant: $F(1,21) = 15.47$, $p = .001$ ($\eta^2 = .424$) indicating, when aggregating across the two groups, a higher estimated mean is obtained at baseline Time1 ($M = 16.30$) than following treatment Time2: ($M = 10.89$). The main effect for group was not significant ($p = .199$, $\eta^2 = .077$). Though the interaction was not significant, the pattern of means was such that a more appreciable decrease in the total ISI score was obtained for the Active group than the Sham group.

  For the 2 x 3 mixed ANOVA, the two-way (first order) interaction is not significant: $F(2, 34) = .84$, $p = .44$ ($\eta^2 = .047$). The main effect for time is significant: $F(2,21) = 8.53$, $p = .001$ ($\eta^2 = .324$) indicating, when aggregating across the two groups, a higher estimated mean is obtained at baseline Time1 ($M = 16.22$) than following treatment Time2: ($M = 11.05$) and post-treatment Time3 ($M = 10.99$). The main effect for group was not significant ($p = .158$, $\eta^2 = .114$). Though the interaction was not significant, the pattern of means was such that a more appreciable decrease in the total ISI score was obtained for the Active group than the Sham group across the first two waves of data collection.
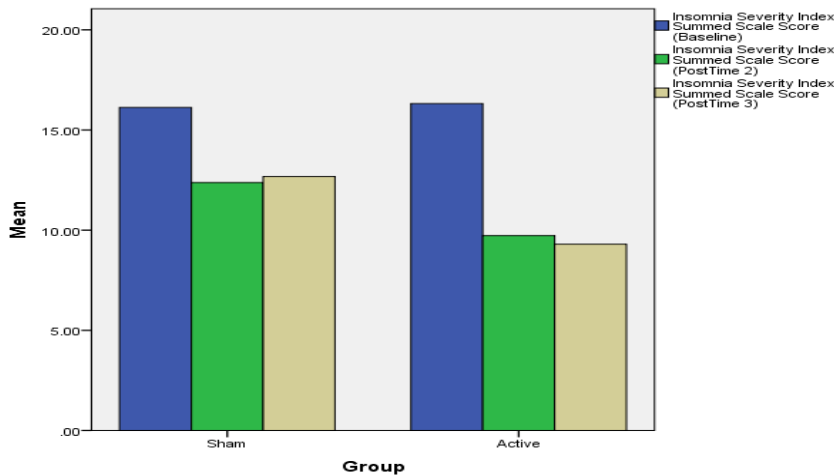
- The 2 x 2 interaction for **Sleep Efficiency** (SE) is not significant: $F(1,21) = .48$, $p = .497$ ($\eta^2 = .022$). The main effect for time is significant: $F(1,21) = 5.64$, $p = .027$ ($\eta^2 = .212$) indicating, when aggregating across the two groups, a higher estimated mean is obtained at after treatment Time2 ($M = 92.61$) than baseline Time1: ($M = 89.99$). The main effect for group was not significant ($p = .964$, $\eta^2 < .001$). Though the interaction was not significant, a more appreciable increase in the SE score was obtained for the Active group than the Sham group.

For the 2 x 3 analysis, comparing the two groups using the baseline Time1, following treatment Time 2, and post-treatment Time 3 measures, the two-way (first order) interaction is not significant: $F(2, 24) = .58$, $p = .57$ ($\eta^2 = .046$). Neither of the main effects were significant for time ($p = .278$, $\eta^2 = .101$) and group ($p = .672$, $\eta^2 = .016$). Though the interaction was not significant, the pattern of means was such that a more appreciable increase in the SE score was obtained for the Active group whereas for the Sham group there was an increased score following treatment Time2 and then a slight decrease for the post-treatment Time3.
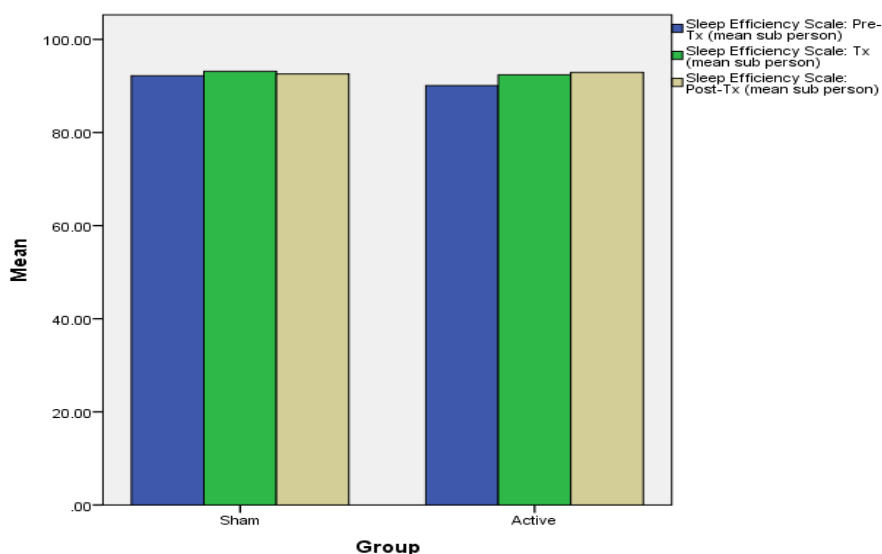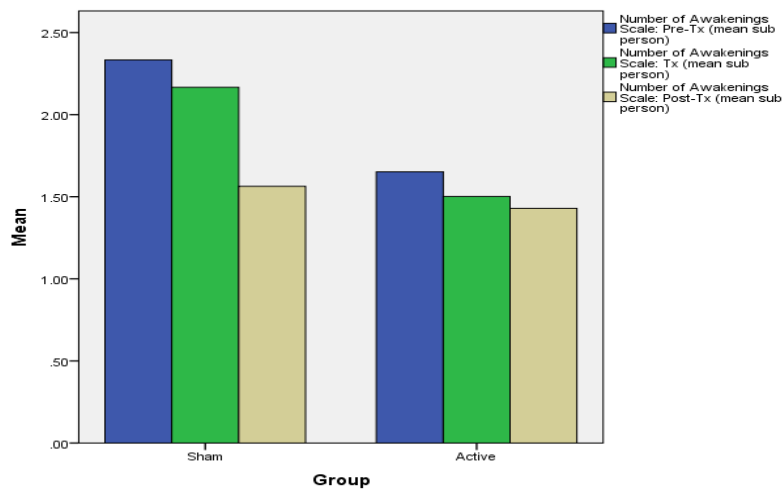
- The 2 x 2 two –way interaction for **Sleep Onset Latency (SOL)** is not significant: $F(1,21) = .32$, $p = .579$ ($\eta2 = .015$). The main effects for time ($p = .099$, $\eta2 = .124$) and group were not significant ($p = .932$, $\eta2 < .001$). Though not significant, a more appreciable decrease in the SOL was obtained for the Active group than the Sham group.

   For the 2 x 3 interaction ,the two-way (first order) interaction is not significant: $F(2,21) = .66$, $p = .524$ ($\eta2 = .052$). The main effects for time ($p = .435$, $\eta2 = .067$) and group were not significant ($p = .715$, $\eta2 = .012$). Though not significant, the pattern of means was such that the Active group had a higher mean at the Time1, approximately the same as the Sham group at Time2, and then the appreciative mean at Time3.
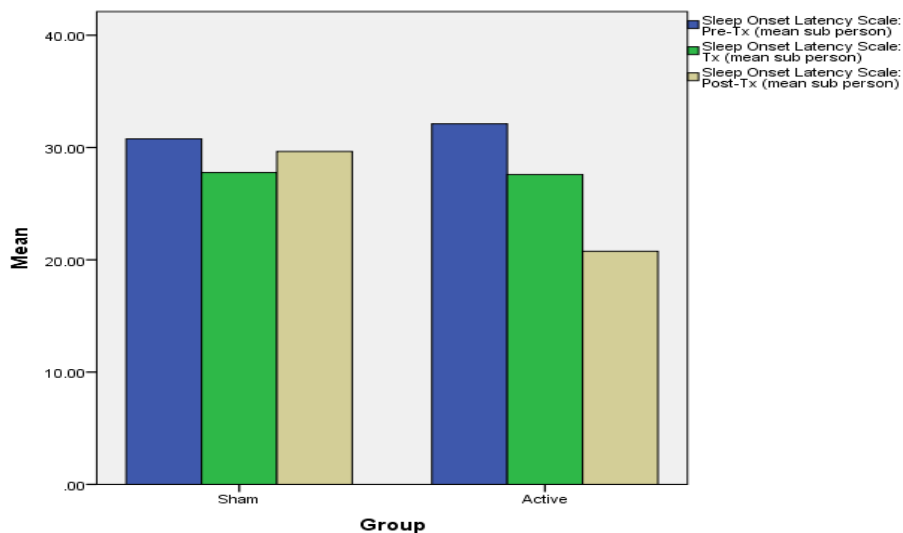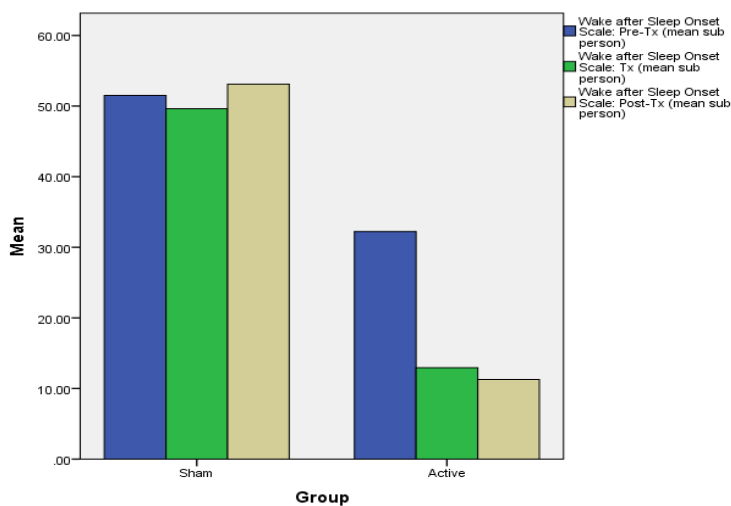

- The two-way interaction for **Number of Awakenings (NAWAK)** is not significant: $F(1,21) = .77$, $p = .39$ ($\eta2 = .035$). The main effect for time is significant: $F(1,21) = 6.95$, $p = .015$ ($\eta2 = .25$) indicating, when aggregating across the two groups, a higher estimated mean is obtained at baseline ($M = 2.02$) than following treatment: ($M = 1.61$). The main effect for group was not significant ($p = .692$, $\eta2 = .008$). Though not significant, the pattern of means was such that a more appreciable decrease in NAWAK was obtained for the Active group than the Sham group.

   For the 2 x 3 interaction, the two-way (first order) interaction is not significant: $F(2, 24) = 1.49$, $p = .245$ ($\eta2 = .111$). The main effect for time is significant: $F(2,24) = 3.94$, $p = .033$ ($\eta2 = .247$) indicating, when aggregating across the two groups, the highest estimated mean is obtained at baseline ($M = 1.99$) with subsequent decreases across each successive wave of measurement ($M = 1.83$ for Time2 and $M = 1.50$ for Time3). The main effect for group was not significant ($p = .401$, $\eta2 = .059$). Though not significant, there was a decrease in the means for both groups with a more appreciable decrease for the Sham group.

- The 2 x 2 two –way interaction for **Wake After Sleep Onset (WASO)** is not significant: $F(1, 16) = 3.45$, $p = .082$ ($\eta2 = .177$). The main effects for time ($p = .082$, $\eta2 = .177$) and group were not significant ($p = .273$, $\eta2 = .075$). Though not significant, the pattern of means was such that a there was a substantive decrease in the WASO score across time for the Active group whereas similar scores are obtained across time for the Sham group.

  The 2 x 3 interaction the two-way (first order) interaction is not significant: $F(2, 12) = .36$, $p = .708$ ($\eta2 = .056$). The main effect for time ($p = .712$, $\eta2 = .055$) was not significant, but there was significance for the group main effect (aggregating across time): $F(1, 5)$, $= 10.34$, $p = .018$ ($\eta2 = .075$) with a higher estimated mean for the Sham group ($M = 51.41$) than the Active group ($M = 18.81$). Though not significant, the pattern of means was such that a there was a substantive decrease in the WASO score across time for the Active group whereas for the Sham group there was a slight decrease at Time2 then increase at Time3. Note that there was significant group main effect (aggregating across time with a higher estimated mean for the Sham group than the Active group).

- The 2 x 2 two –way interaction for **Overall Sleep Quality (SQ)** is not significant: $F(1,21) = 2.71$, $p = .115$ ($\eta2 = .114$). The main effect for time is significant: $F(1,21) = 28.26$, $p < .001$ ($\eta2 = .574$) indicating, when aggregating across the two groups, a lower estimated mean is obtained at Time1 baseline (M = 4.75) than Time2: (M = 5.93). The main effect for group was not significant ($p = .846$, $\eta2 = .002$). Though not significant, the pattern of means was such that a more appreciable increase in Overall SQ was obtained for the Sham group than the Active group across the two waves of data collection.

  For the 2 x 3 interaction the two-way (first order) interaction is not significant: $F(2,21) = .23$, $p = .779$ ($\eta2 = .019$). The main effect for time is significant: $F(1,21) = 5.91$, $p = .008$ ($\eta2 = .33$) indicating, when aggregating across the two groups, a lower estimated mean is obtained at Time1 baseline (M = 4.68) and then similar higher means at Time2 (M = 5.84) and Time3 (M = 5.83). The main effect for group was not significant ($p = .291$, $\eta2 = .092$). Though not significant, the pattern of means was such that there are successively higher means in Overall SQ for the Active group whereas there is a slight decrease at the Post-TX measure for the Sham group.
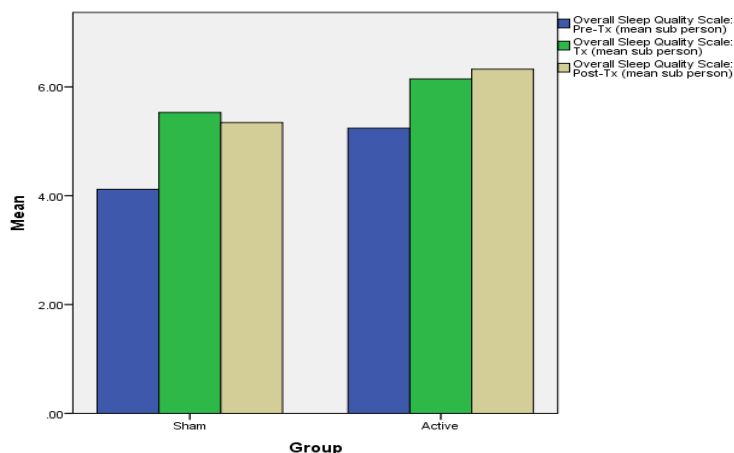
Question #3: Describe socio-demographic characteristics (including rank) and other factors (trait anxiety, state anxiety, family and self-history of insomnia, perceived stress, frequency and length of deployment, and sleep hygiene) as potential predictors of a successful treatment response.

Multiple regression was used to predict the Insomnia Severity Index (ISI) with a set of predictors for this aim. Given the small sample size, it was decided to pare down the number of predictors, and conduct analysis separately at each wave of data collection. The variables to be used as predictors are as follows:

1. Self history of sleep problems: will only use history of insomnia
2. Trait anxiety (TSTAI)
3. Perceived stress (PSS)
4. Group (treatment/active vs. control/sham)

- When conducting hierarchical regression with **ISI at Time1 as the outcome**, at the first step of variable entry (i.e., history of insomnia, PSS, and TSTAI), $R^2 = .153$ (i.e., 15.3% of the variability is accounted for in explaining the outcome). Though that is what would be considered to be a medium effect size in multiple regression, significance was not obtained, At the 2nd step of variable entry (i.e., the grouping variable) the incremental variability was only $R^2 = .01$ and it was not significant. 15.4% of the variability was accounted for by the full model. When examining the partial regression coefficients at both steps of variable entry, no variables were significant. However, history of insomnia had the largest bivariate correlation (r =.3) and partial correlation (rp = .292) at the final step of variable entry. Also, improvement in model fit (though significance still not obtained) was obtained when nonlinear terms for PSS and TSTAI were added to the model, and also, when an outlying residual from the initial model was omitted.

Model Summary[c]

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	R Square Change	F Change	df1	df2	Sig. F Change
					Change Statistics				
1	.391[a]	.153	.026	2.59091	.153	1.202	3	20	.335
2	.392[b]	.154	-.025	2.65685	.001	.020	1	19	.890

a. Predictors: (Constant), PSS_sc Perceived Stress Scale-10 summed scale score, SelfInsomnia Sleep History--Self: Insomnia, TSTAI_sc Trait state trait anixety Index Summed scale score

b. Predictors: (Constant), PSS_sc Perceived Stress Scale-10 summed scale score, SelfInsomnia Sleep History--Self: Insomnia, TSTAI_sc Trait state trait anixety Index Summed scale score, Group

c. Dependent Variable: ISI_sc Insomnia Severity Index Summed Scale Score (Baseline)

Coefficients[a]

Model		Unstandardized Coefficients B	Std. Error	Standardized Coefficients Beta	t	Sig.	95.0% Confidence Interval for B Lower Bound	Upper Bound	Correlations Zero-order	Partial	Part	Collinearity Statistics Tolerance	VIF
1	(Constant)	13.207	2.747		4.807	.000	7.476	18.938					
	SelfInsomnia Sleep History--Self: Insomnia	1.454	1.067	.282	1.363	.188	-.771	3.680	.300	.292	.281	.990	1.010
	TSTAI_sc Trait state trait anixety Index Summed scale score	.046	.093	.129	.502	.621	-.147	.240	.228	.111	.103	.640	1.562
	PSS_sc Perceived Stress Scale-10 summed scale score	.059	.100	.152	.588	.563	-.149	.267	.256	.130	.121	.635	1.574
2	(Constant)	13.151	2.846		4.620	.000	7.193	19.108					
	SelfInsomnia Sleep History--Self: Insomnia	1.472	1.101	.285	1.337	.197	-.833	3.777	.300	.293	.282	.977	1.024
	TSTAI_sc Trait state trait anixety Index Summed scale score	.047	.095	.130	.494	.627	-.152	.246	.228	.113	.104	.640	1.563
	PSS_sc Perceived Stress Scale-10 summed scale score	.055	.106	.142	.521	.609	-.166	.276	.256	.119	.110	.596	1.679
	Group	.159	1.136	.031	.140	.890	-2.220	2.537	.065	.032	.029	.911	1.098

a. Dependent Variable: ISI_sc Insomnia Severity Index Summed Scale Score (Baseline)

- When conducting hierarchical regression with **ISI at Time2 as the outcome**, at the first step of variable entry (i.e., history of insomnia, PSS, and TSTAI), $R^2 = .078$ (i.e., 7.8% of the variability is accounted for in explaining the outcome) and significance was not obtained. At the 2nd step of variable entry (i.e., the grouping variable) the incremental variability was $R^2 = .061$ and it was not significant. 13.9% of the variability was accounted for by the full model. When examining the partial regression coefficients at both steps of variable entry, no variables were significant. However, the grouping variable had the largest bivariate correlation (r = -29) and partial correlation (rp = .258) at the final step of variable entry. Also, as documented in the report, improvement in model fit (though significance still not obtained) was obtained when nonlinear terms for PSS and TSTAI were added to the model.

Model Summary^c

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics				
					R Square Change	F Change	df1	df2	Sig. F Change
1	.279^a	.078	-.068	5.65496	.078	.536	3	19	.664
2	.373^b	.139	-.052	5.61385	.061	1.279	1	18	.273

a. Predictors: (Constant), PSS2_sc Perceived Stress Scale-10 summed scale score (Posttime 2), SelfInsomnia Sleep History--Self: Insomnia, TSTAI_sc Trait state trait anixety Index Summed scale score

b. Predictors: (Constant), PSS2_sc Perceived Stress Scale-10 summed scale score (Posttime 2), SelfInsomnia Sleep History--Self: Insomnia, TSTAI_sc Trait state trait anixety Index Summed scale score, Group

c. Dependent Variable: ISI2_sc Insomnia Severity Index Summed Scale Score (PostTime 2)

Coefficients^a

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95.0% Confidence Interval for B		Correlations			Collinearity Statistics	
		B	Std. Error	Beta			Lower Bound	Upper Bound	Zero-order	Partial	Part	Tolerance	VIF
1	(Constant)	17.631	6.189		2.849	.010	4.677	30.585					
	SelfInsomnia Sleep History--Self: Insomnia	-1.301	2.381	-.120	-.547	.591	-6.284	3.681	-.113	-.124	-.120	.998	1.002
	TSTAI_sc Trait state trait anixety Index Summed scale score	-.169	.217	-.223	-.777	.447	-.623	.286	-.250	-.175	-.171	.587	1.703
	PSS2_sc Perceived Stress Scale-10 summed scale score (Posttime 2)	-.052	.323	-.047	-.162	.873	-.727	.623	-.185	-.037	-.036	.587	1.704
2	(Constant)	18.290	6.172		2.963	.008	5.323	31.256					
	SelfInsomnia Sleep History--Self: Insomnia	-1.373	2.364	-.127	-.581	.569	-6.340	3.594	-.113	-.136	-.127	.998	1.002
	TSTAI_sc Trait state trait anixety Index Summed scale score	-.169	.215	-.224	-.786	.442	-.622	.283	-.250	-.182	-.172	.587	1.703
	PSS2_sc Perceived Stress Scale-10 summed scale score (Posttime 2)	.041	.331	.037	.124	.902	-.654	.736	-.185	.029	.027	.550	1.817
	Group	-2.796	2.472	-.261	-1.131	.273	-7.989	2.397	-.290	-.258	-.247	.899	1.113

a. Dependent Variable: ISI2_sc Insomnia Severity Index Summed Scale Score (PostTime 2)

- When conducting hierarchical regression with **ISI at Time3 as the outcome** at the first step of variable entry (i.e., history of insomnia, PSS, and TSTAI), $R^2 = .26$ and though it is a relatively large effect size for multiple regression, significance was not obtained. At the 2nd step of variable entry (i.e., the grouping variable) the incremental variability was $R^2 = .088$ and it was not significant. 34.8% of the variability was accounted for by the full model. When examining the partial regression coefficients at both steps of variable entry, the TSTAI total score was significant at both the first and second step of variable entry and it also yielded the largest bivariate correlation (r = -.502) and partial correlation (rp = -.508) at the final step of variable entry.

Model Summary^c

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics				
					R Square Change	F Change	df1	df2	Sig. F Change
1	.510^a	.260	.113	4.74355	.260	1.761	3	15	.198
2	.590^b	.348	.162	4.60965	.088	1.884	1	14	.191

a. Predictors: (Constant), PSS3_sc Perceived Stress Scale-10 summed scale score (Posttime 3), SelfInsomnia Sleep History--Self: Insomnia, TSTAI_sc Trait state trait anixety Index Summed scale score

b. Predictors: (Constant), PSS3_sc Perceived Stress Scale-10 summed scale score (Posttime 3), SelfInsomnia Sleep History--Self: Insomnia, TSTAI_sc Trait state trait anixety Index Summed scale score, Group

c. Dependent Variable: ISI3_sc Insomnia Severity Index Summed Scale Score (PostTime 3)

Coefficients[a]

| Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.	95.0% Confidence Interval for B		Correlations			Collinearity Statistics	
		B	Std. Error	Beta			Lower Bound	Upper Bound	Zero-order	Partial	Part	Tolerance	VIF
1	(Constant)	22.386	5.291		4.231	.001	11.107	33.664					
	SelfInsomnia Sleep History--Self: Insomnia	.014	2.186	.001	.006	.995	-4.645	4.673	-.026	.002	.001	.994	1.006
	TSTAI_sc Trait state trait anixety Index Summed scale score	-.362	.162	-.543	-2.231	.041	-.707	-.016	-.502	-.499	-.495	.833	1.200
	PSS3_sc Perceived Stress Scale-10 summed scale score (Posttime 3)	.081	.196	.100	.411	.687	-.337	.499	-.121	.106	.091	.833	1.201
2	(Constant)	23.393	5.194		4.504	.000	12.253	34.533					
	SelfInsomnia Sleep History--Self: Insomnia	-.156	2.128	-.016	-.073	.943	-4.720	4.408	-.026	-.020	-.016	.991	1.009
	TSTAI_sc Trait state trait anixety Index Summed scale score	-.348	.158	-.522	-2.205	.045	-.686	-.009	-.502	-.508	-.476	.830	1.205
	PSS3_sc Perceived Stress Scale-10 summed scale score (Posttime 3)	.111	.192	.138	.581	.571	-.300	.523	-.121	.153	.125	.821	1.218
	Group	-2.985	2.175	-.301	-1.373	.191	-7.649	1.679	-.340	-.344	-.296	.970	1.031

a. Dependent Variable: ISI3_sc Insomnia Severity Index Summed Scale Score (PostTime 3)

Supplemental data analysis was conducted for the Beck Anxiety Inventory (BAI), the Perceived Stress Scale (PSS), the State Trait Anxiety Inventory (STAI) and to test the relationship of group membership with self-report of history of insomnia.

- For supplementary analysis for the Beck Anxiety Inventory (BAI), the 2 x 2 mixed ANOVA, comparing the two groups using the baseline Time1 and following treatment Time2 measures, the two-way (first order) interaction was not significant. The main effect for time was significant indicating, when aggregating across the two groups, a higher estimated mean is obtained at baseline Time1 ($M = 5.91$) than following treatment Time2 ($M = 3.36$). Both groups exhibited similar decrease in means over time. For the 2 x 3 mixed ANOVA (DV = BAI) the two-way (first order) interaction was not significant, but the main effect for time was *with* the highest estimated mean obtained at Time1 ($M = 6.05$) and lowest at Time2 ($M = 3.16$). Both groups exhibited similar trajectories excepting at the last wave of data collection there was a slight increase in the mean for the Active group and a decrease for the Sham group.
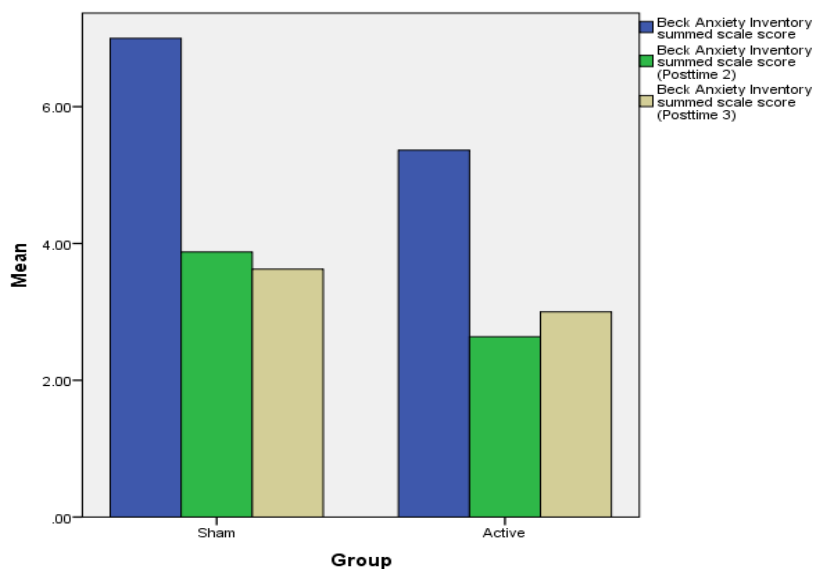
- For supplementary analysis for the Perceived Stress Scale (PSS), the 2 x 2 mixed ANOVA comparing the two groups using the baseline Time1 and following treatment Time2 measures, the two-way (first order) interaction is not significant. The main effect for time is significant indicating, when aggregating across the two groups, a higher estimated mean is obtained at Time1 ($M = 12.30$) than Time2 ($M = 9.22$). Both groups exhibited similar decrease in means over time. There were no significant effects for the 2 x 3 mixed ANOVA.
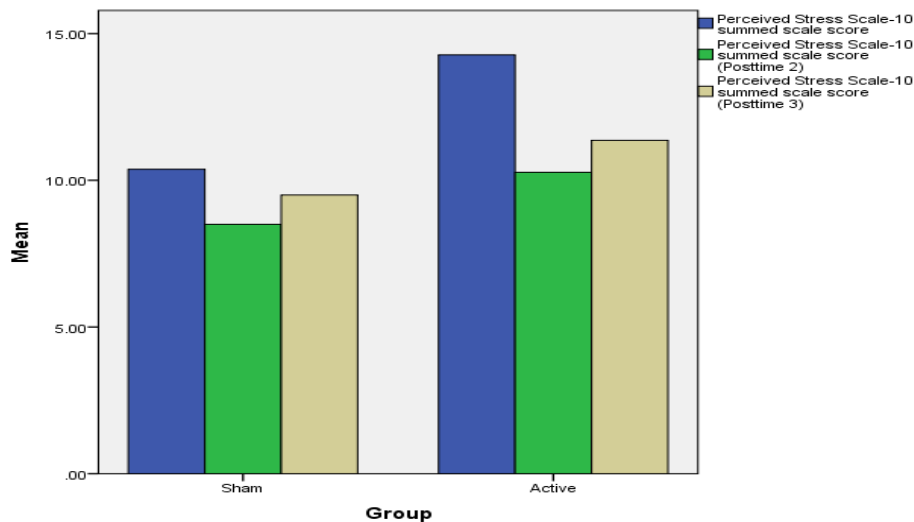
- For supplementary analysis for the State Trait Anxiety Inventory (STAI) the mean differences between the groups was not significant. Though not significant the Active group had a higher mean ($M = 35.56$) than the Sham group ($M = 33.54$).

Descriptive Statistics

Dependent Variable: TSTAI_sc Trait state trait anixety

Group	Mean	Std. Deviation	N
.0 Sham	33.5417	7.94143	12
1.0 Active	35.5833	6.76163	12
Total	34.5625	7.28804	24

- For supplementary analysis a 2 x 2 chi-squared test was conducted tested the relationship of group membership and self-report of history of insomnia. Though the findings were not significant, 50% (n = 6) in the Sham group reported history of insomnia whereas 41.7% (n = 5) in the Active group did so (Relative Risk = 1.2).

Effect of problems or obstacles on the results:
Low recruitment and retention rate affected the data analyses and overall implications of the findings for Question #2 and Question #3.

Limitations:
Limitations to the study are due to the strict inclusion criteria and intensive data collection in the study design, which hindered recruitment and retention of participants leading to not meeting the required number of participants per power analysis.

Conclusion:
While well received from the participants in the acceptability of the treatment modality, feasibility as evidenced by recruitment and retention was not optimal based on the strict criteria. Thus, the main lesson learned from this study is that "pure" insomniacs are far and a few between and insomnia is often a co-morbid condition.

Trends in the data for the small sample size, however, show an overall improvement in Insomnia Severity Index and the self-reported sleep parameters for the Active group over the Sham group (with an exception of the number of awakenings). Of note, when aggregating the group means for the ISI total score, SQ, and the BAI, the main effects for time were significant across the three phases of the study; potentially indicating that participation in the study (regardless of group) had an effect on the overall outcomes.

Significance of Study or Project Results to Military Nursing

Insomnia is linked to impaired cognitive and immune functions, decreased quality of life, and increased accidents. Insomnia is well established in the general population both as a risk factor for and as a symptom PTSD, anxiety, and depression. CBT-I and pharmacotherapies are both efficacious treatments for the improvement of sleep. However, CBT-I is often time-consuming, requires trained clinicians or health care providers, and is not readily accessible. CBT-I requires that individuals keep a consistent daily sleep and wake schedule, which would be difficult for Service members deployed in war zones. Hypnotic drugs have undesirable side effects and are recommended primarily for a short-term use. These drugs are not ideal in a fast-paced environment with unpredictable sleeping conditions. Few data are available regarding soldiers with insomnia and no studies are available using a safe, portable device such as the CES in treatment of soldiers with insomnia. Hence, identification of insomnia and early treatment with a readily available, easy-to-use device with minimal adverse effects by military nurses and other healthcare providers can ensure timely treatment of soldiers with insomnia. This pilot study of treatment effect of CES is a first step in the development of research program with potential to assist in the management of insomnia and co-morbid conditions in soldiers.

Changes in Clinical Practice, Leadership, Management, Education, Policy, and/or Military Doctrine that Resulted from Study or Project

Nothing Significant to Report

References Cited
None

Summary of Dissemination

Type of Dissemination	Citation	Date and Source of Approval for Public Release
Publications	None	
Publications in Press	None	
Published Abstracts	None	
Podium Presentations	Hopkinson, S. Researching Complementary and Alternative Medicine for Sleep Disorders ERMC Fall Conference; Garmisch, Germany Garner, B. Cranial Electrotherapy Stimulation (CES) in Servicemembers with Insomnia: A Pilot Study TSNRP Dissemination Course; San Antonio, TX	Nov 2014 – LRMC PAO & OPSEC Sep 2014 – OTSG
Poster Presentations	Hopkinson, S., Garner, B., & Ladwig, J. Cranial Electrotherapy Stimulation (CES) in Military Beneficiaries with Insomnia: A Pilot Study EAMNE—European African Military Nursing Exchange; Garmisch, Germany	Apr 2015 – LRMC PAO & OPSEC
Media Reports	None	
Other	None	

Reportable Outcomes

Reportable Outcome	Detailed Description
Applied for Patent	None
Issued a Patent	None
Developed a cell line	None
Developed a tissue or serum	None
Developed a data registry	None

Recruitment and Retention Table

Recruitment and Retention Aspect	Number
Subjects Projected in Grant Application	50
Subjects Available	
Subjects Contacted or Reached by Approved Recruitment Method	230
Subjects Screened	230
Subjects Ineligible	174
Subjects Refused	0
Human Subjects Consented	55
Subjects Who Withdrew	1
Subjects Who Completed Study	23
Subjects With Complete Data	14
Subjects with Incomplete Data	9

Demographic Characteristics of the Sample

Characteristic (Eligible for Intervention n = 27)	
Age (yrs)	40 ± 12
Women, n (%)	13 (48%)
Race	
White, n (%)	17 (63%)
Black, n (%)	7 (26%)
Hispanic or Latino, n (%)	3 (11%)
Native Hawaiian or other Pacific Islander, n (%)	0 (0%)
Asian, n (%)	0 (0%)
Other, n (%)	0 (0%)
Military Service or Civilian	
Air Force, n (%)	12 (44%)
Army, n (%)	13 (48%)
Marine, n (%)	0 (0%)
Navy, n (%)	1 (4%)
Civilian, n (%)	0 (0%)
Missing data, n (%)	1 (4%)
Service Component	
Active Duty, n (%)	12 (44%)
Reserve, n (%)	1 (4%)
National Guard, n (%)	6 (22%)
Retired Military, n (%)	2 (7%)
Prior Military but not Retired, n (%)	0 (0%)
Military Dependent, n (%)	6 (22%)
Civilian, n (%)	0 (0%)